

***Sponsored by the Arizona Translational Resource Network***

**IRB Networking and Education Forum – Fall Program**

**IRB Audits**

October 31, 2006

The IRB Networking and Education Forum is a volunteer group organized by the Arizona Translational Resource Network (AZTransNet). The AZTransNet is supported by the Arizona Translational Research Pathway Project, funded by the Arizona Biomedical Research Commission and the Flinn Foundation. The IRB Networking and Education Forum is designed to establish a common understanding of issues and create greater consistency in approaches to Institutional Review Boards (IRBs) issues in Arizona. The IRB Networking and Education Forum is focused on IRB professionals and other individuals working in research administration.

The first IRB Networking and Education Forum will focus on IRB audits: what triggers an audit, how to avoid an audit, how to handle external audits and investigations when they occur, when to conduct internal audits.

The IRB Networking and Education Forum will utilize the Arizona Telemedicine Network, so that participants from Tucson, Phoenix and Flagstaff can join each other visually for the program. The program sites include:

- Phoenix: Arizona Health Sciences Center, 600 East Van Buren St., Room 2208
- Tucson: Arizona Health Sciences Center, 1501 N. Campbell Ave., Room 3230
- Flagstaff: Flagstaff Medical Center, Children's Health Center, 1200 N. Beaver St.

If you would like to ask “anonymous” questions of the panelists, please forward them to Pam Mitchell at (831) 901-4011; [Pimitchell@aol.com](mailto:Pimitchell@aol.com). **We hope you join us!**

**Agenda**

- Sign-in and networking breakfast: 8:30 – 9:15 am
- Welcome and Introduction to the Arizona Translational Resource Network and IRB Networking and Education Forum Project: 9:15-9:30
  - Pam Mitchell, Battelle
- Keynote Speaker: Navigating an FDA Audit 9:30 – 10:15
  - Dr. Sandra Shire, U.S. Food and Drug Administration
- Facilitated Question and Answer Session: 10:15 – 10:30
  - Kristen Rosati, Esq., Coppersmith Gordon Schermer Owens & Nelson PLC
- Break: 10:30 – 10:45 am
- OHRP Audits and Investigations: 10:45- 11:05
  - Linda Mottle, Director, Clinical Research Program, Gateway Community College
- Internal Audit Best Practices: 11:05- 11:25
  - Rebecca Dahl, Director, Human Subject Protection, University of Arizona

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- Facilitated Question and Answer Session: 11:25 – 11:40
  - Kristen Rosati, Esq., Coppersmith Gordon Schermer Owens & Nelson PLC
- Program Close: 11:40 – 12:00
  - Assess program value
  - Identify winter program topics
  - IRB Networking at the Biospecimen Research Retreat: January 31, 2007

**Questions about the IRB Networking and Education Forum?**

Contact Pam Mitchell at (831) 901-4011 or [pimitchell@aol.com](mailto:pimitchell@aol.com).